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Date: May 18, 2005

Phone:

Pages: 8 (including coversheet)

Re: Appeal No. 2004-2313
Application Serial Number: 09/997,191
Atty. Dkt. No. LEX-0270-USA

CC: File

•Comments:

Please find attached a Request for Rehearing Under 37 C.F.R. § 1.197(b) in reference to the above-referenced appeal. Please contact me at the number shown above if there are any questions.

CERTIFICATION OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being filed with Dianne Maggard of the United States Patent and Trademark Office by facsimile transmission on May 18, 2005 to facsimile telephone number (571) 273-0300.

David W. Hibler

41,071
(Reg. No.)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant(s):	Walke *et al.*	Group Art Unit:	1647
Application No.:	09/997,191	Appeal No.:	2004-2313
Filed:	11/20/2001	Examiner:	R. DeBerry
Title:	Novel Human Wnt-Family Protein and Polynucleotides Encoding the Same	Atty. Docket No.:	LEX-0270-USA

REQUEST FOR REHEARING UNDER 37 C.F.R. § 1.197(b)

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants acknowledge the receipt of the Decision on Appeal ("the Decision") in the above-referenced case, mailed on March 18. 2005. which has been carefully reviewed and studied. Appellants herein request rehearing, as discussed in detail below.

As set forth in 37 C.F.R. § 1.197(b), the time limit for filing a request for rehearing is "within two months from the date of the original decision". The present request for rehearing is therefore timely filed, and Appellants believe no fees are due in connection with this request. However, the Commissioner is authorized to charge any required fees or credit any overpayment to Deposit Account No. 50-0892.

REQUEST FOR REHEARING

As set forth in 37 C.F.R. § 1.197(b), "(t)he request for rehearing must state with particularity the points believed to have been misapprehended or overlooked in rendering the decision". Appellants respectfully submit that the Board appears to have misapprehended Appellants' arguments concerning several of the credible, specific, substantial, and well-established utilities set forth in the Appeal Brief in the present case. Specifically: 1) Appellants' assertion that the presently claimed nucleotide sequence, SEQ ID NO:1, encodes a human Wnt-14 protein, SEQ ID NO:2, that is involved in cancer and development; 2) Appellants' assertion that the presently described polymorphisms have utility in forensic analysis; and 3) Appellants' assertion that the presently claimed nucleotide sequence has utility for monitoring gene expression patterns using high-throughput DNA chips.

With regard to Appellants' assertion that the presently claimed nucleotide sequence, SEQ ID NO:1, encodes a human Wnt-14 protein, SEQ ID NO:2, that is involved in cancer and development, while noting that "(t)he specification admits that 'Wnt-family proteins ... have been implicated in a number of biological processes and anomalies, such as blood cell formation, cancer, homeostasis, development, weight regulation, and inflammation'", the Decision states that "(t)he specification does not disclose which, if any, of these processes have been associated with Wnt-14, nor does the specification provides (*sic*; provide) any information regarding the biological function or activity of the polypeptide encoded by the instantly claimed nucleic acids" (the Decision at page 13). The Decision acknowledges Appellants' argument in the Appeal Brief that

> the specification as originally filed states that the presently claimed sequence has a role in "cancer" (specification at page 1, line 26), a role that has been confirmed by Kirikoshi *et al.* (*Int. J. Oncol.* 19:1221-1225, 2001 ...), as well as a role in "development" (specification at page 1, line 26), a role that has been confirmed by Hartmann and Tabin (*Cell* 104:341-351, 2001 ...). Appellants pointed out that given the well-established biological and medical relevance of Wnt-14, those of skill in the art would readily appreciate the utility of the present sequence in numerous applications, as described herein below and in the specification as originally filed

(the Decision at page 13, emphasis in original), but states that "(w)e do not find this argument persuasive" because "(t)he references cited by Appellants were published after the effective filing date of the instant application (November 21, 2000)", and "(w)hether a claimed invention is supported by

a disclosure of utility sufficient to satisfy 35 U.S.C. § 101 is determined as of the filing date of the application". In support, the Board cites *In re Brana* (34 USPQ2d 1436 (Fed. Cir. 1995); "*Brana*"); "(e)nablement, or utility, is determined as of the application filing date" (the Decision at page 13).

Appellants respectfully submit that the Board has misapprehended the holding in *Brana*. This is most readily shown by examining the very next line in *Brana* following the quote utilized by the Board ("(e)nablement, or utility, is determined as of the application filing date"), which states "(t)he Kluge declaration, though dated after applicants' filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification" (*Brana*, *supra*). Thus, rather than supporting the Board's position, *Brana* actually supports **Appellants'** position, since the references in question "though dated after applicants' [effective] filing date, can be used to substantiate any doubts as to the asserted utility since this pertains to the accuracy of a statement already in the specification".

Appellants respectfully point out that Appellants' position is also supported by another case cited and quoted by the Board in the Decision, *In re Jolles* (628 F.2d 1322, 206 USPQ 885, (CCPA 1980); "*Jolles*"). As set forth in the Decision:

> the CCPA reversed a rejection for lack of utility in *In re Jolles*. The applicants in *Jolles* claimed pharmaceutical compositions that were disclosed to be useful in treating acute myoblastic leukemia. The active ingredient in the compositions were closely related to daunorubicin and doxorubicin, both of which were 'well recognized in the art as valuable for use in cancer chemotherapy'. The applicant also submitted declaratory evidence [of post-filing experiments],

(the Decision at page 9, citations omitted). Thus, the holding in *Jolles* establishes that only the assertion of utility must be present in the specification as originally filed, and, further, that post-filing evidence can be relied upon to support the original assertion of utility. In view of the holdings in both *Brana* and *Jolles*, it is clear that the Board's stated conclusions are inconsistent with the cited legal precedent.

Given that the legal basis for the Board's decision requires reconsideration, the remaining scientific/procedural issue is whether the United States Patent and Trademark Office ("the USPTO") considers "structural similarity" to Wnt-14, which the skilled artisan would clearly believe to have a credible, specific, substantial, and well-established utility, sufficient to establish a patentable utility for the claimed sequence. Appellants pointed out in the Appeal Brief that Example 10 of the Revised Interim Utility Guidelines Training Materials (see **Exhibit D** of the Appeal Brief), which has been set forth by the USPTO, clearly establishes that a rejection under 35 U.S.C. § 101 as allegedly lacking a

patentable utility, and under 35 U.S.C. § 112, first paragraph as allegedly unusable by the skilled artisan due to the alleged lack of patentable utility, is not proper when a full length sequence has a similarity score greater than 95% to a protein having a known function. Appellants submit, as set forth in the Appeal Brief at page 5, that as the presently claimed "full length sequence" has a similarity score of "greater than 95%" (in fact, nearly 100% identity) to a protein having a known function (specifically, to a sequence that has been annotated by third party scientists *wholly unaffiliated with Appellants* as Wnt-14; see **Exhibit A** of the Appeal Brief, that has been confirmed to be associated with a biological function (at least development, and also cancer) consistent with that asserted by Appellants in the specification as originally filed), the present facts **directly**, and in fact exceed, the stringency of the test described by the USPTO as clearly meeting the utility standards, Example 10 of the Revised Interim Utility Guidelines Training Materials. Therefore, the presently claimed invention clearly meets the requirements for utility under both 35 U.S.C. § 101 and 35 U.S.C. § 112.

Regarding Appellants' assertion that the presently described polymorphisms have utility in forensic analysis, the Decision states that:

> assuming that those skilled in the art would have understood the specification's reference to "forensic biology" to refer to the polymorphisms in SEQ ID NO:1, Appellants have not shown that the skilled worker would have found the specific polymorphisms present in SEQ ID NO:1 - without analysis of their degree of variability in the human population and without associating them with any other genetic marker - to be useful as argued

(the Decision at page 15, emphasis in original). However, this appears to misapprehend Appellants' position. Rather, as Appellants clearly set forth in the Appeal Brief at pages 9 and 10, the use of the presently described polymorphisms in forensic analysis does not require any information at all about the ultimate biological function of the encoded protein, or require that the mutation cause a "disease or condition". Further, Appellants set forth numerous instances where the presently described polymorphisms are useful in the present form, without any information about "their degree of variability in the human population and without associating them with any other genetic marker". Specifically, at page 9 of the Appeal Brief, Appellants pointed out that the presently described polymorphisms can be used to "rule out suspects in many criminal cases", as well as to "rule out individuals suspected of fathering a particular child". The skilled artisan readily understands that in such a forensic analysis, the presence or absence of the polymorphic marker is all that is required. If a suspect lacks one or more of the instantly described polymorphic markers present in DNA from a criminal case or in a paternity

determination, that suspect is ruled out. No further information concerning "their degree of variability in the human population" or "associating them with any other genetic marker" is required. Thus, Appellants submit that the presently claimed sequences, and the polymorphisms therein contained, are useful in forensic analysis in their currently available form, and thus meet the utility requirements of both 35 U.S.C. § 101 and 35 U.S.C. § 112.

Finally, with regard to Appellants' assertion that the presently claimed nucleotide sequence has utility for monitoring gene expression patterns using high-throughput DNA chips, the Board states:

> Under Appellants' rule, then, any polynucleotide from an expressed gene would be patentable if it was adequately described in the specification and was not disclosed or suggested in the prior art. This standard, however, is not the one set by Congress, which requires that a patentable invention also be useful and fully enabled, nor is it the standard that has been consistently applied by the courts. In addition, the flood of DNA patents that would result from adoption of Appellants' rule could doom the potential contribution of microarrays to biological research .... The practical effect of Appellants' utility standard, however, would be that making a microarray with 1000 genes represented on it would require investigating each of the DNA sequences (and subsequences) on the gene chip to ensure that it was not the subject of someone else's patent. For each of the DNAs that was the subject of someone else's patent claim, a license would have to be negotiated - potentially thousands of such negotiations for the finished product

(the Decision bridging pages 22 and 23, emphasis in original). Appellants readily agree that in order to be patentable an invention must "be useful and fully enabled", but respectfully point out that there are a number of flaws in the reasoning set forth above. First, Appellants point out that based on the present utility requirement (which the Board believes is different from "Appellants' rule"), there currently exists hundreds, if not thousands, of valid, issued U.S. Patents covering nucleic acid sequences. Thus, "making a microarray with 1000 genes represented on it" **presently requires** "investigating each of the DNA sequences (and subsequences) on the gene chip to ensure that it" **is** "not the subject of someone else's patent", and "(f)or each of the DNAs that" **is** "the subject of someone else's patent claim, a license" **has** "to be negotiated". However, the presence of such issued U.S. Patents has not "doom[ed] the potential contribution of microarrays to biological research", as microarrays continue to be manufactured and used in biological research **every day**. Thus, the "industry gridlock likely to result", which "has been termed a 'tragedy of the anticommons'" (the Decision at page 23), has clearly **not** come to pass. Thus, it is abundantly clear that "Appellants' rule" for meeting the utility requirements

under 35 U.S.C. § 101 and 35 U.S.C. § 112 is actually the exact same standard of utility that the USPTO has followed for years, and continues to follow to this very day.

Next, the Board states that "(a)lthough each nucleotide in the DNA chip contributes to the data generated by the DNA chip overall, the contribution of a single polynucleotide - its data point - is only a tiny contribution to the overall picture", and that "(t)he Brenner Court held that § 101 sets more than a de minimus standard for utility" (the Decision at page 19). Appellants respectfully point out that neither 35 U.S.C. § 101, nor any decision of the Supreme Court or the Federal Circuit, clearly elucidates what constitutes a *de minimus* utility. Using the reasoning set forth by the Board, a DNA chip that contained a particular nucleic acid sequence amongst 1000 DNA sequences is *de minimus*, but a DNA chip that contained a particular nucleic acid sequence amongst 5 or 10 DNA sequences would likely not be considered *de minimus*. In fact, the heightened burden placed on nucleic acid sequences for meeting the utility requirements under 35 U.S.C. § 101 and 35 U.S.C. § 112 is exactly what leads to the current situation of attempting to determine how thin to slice an apple before it can no longer be considered an apple.

Finally, Appellants point out that all articles of manufacture composed of multiple parts requires "investigating each" part "to ensure that it was not the subject of someone else's patent". As just two notable examples, automobiles containing a particular intermittent windshield wiper system, and satellites constructed and launched by the U.S. Government with a particular stabilization system, should have been "investigated" to ensure that none of the parts were "the subject of someone else's patent". Nevertheless, even in spite of U.S. Patents to intermittent windshield wipers and satellite stabilizing systems, innovations in both of these areas has not been hindered to create "industry gridlock". Further, using the reasoning set forth by the Board in the preceding paragraph, the intermittent windshield wiper would likely be considered a "a tiny contribution to the overall picture" of the automobile, yet was found to meet the utility requirements under 35 U.S.C. § 101 and 35 U.S.C. § 112. In brief, practical experience has largely rendered moot the hypothetical policy considerations discussed in the Board's decision. Thus, Appellants submit that the presently claimed invention meets the utility requirements of both 35 U.S.C. § 101 and 35 U.S.C. § 112.

As set forth in the Appeal Brief, Appellants need only make one credible assertion of utility to meet the requirements of 35 U.S.C. § 101 (*Raytheon v. Roper*, 220 USPQ 592 (Fed. Cir. 1983); *In re Gottlieb*, 140 USPQ 665 (CCPA 1964); *In re Malachowski*, 189 USPQ 432 (CCPA 1976); *Hoffman v. Klaus*, 9 USPQ2d 1657 (Bd. Pat. App. & Inter. 1988). Thus, based on the arguments

above, as well as those set forth in the Appeal Brief, Appellants contend that the presently claimed sequence clearly meets the utility requirements of both 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph, as defined by established legal precedent, as a matter of scientific analysis and procedure, and even as a matter of practically proven policy.

Therefore, given that assertions of credible, specific, substantial, and well-established utilities are set forth by Appellants in the present Appeal Brief, which appear to have been misapprehended by the Board, Appellants respectfully request a rehearing of the present Appeal Brief, and for the Board to overrule the rejections of claims 1-6 under 35 U.S.C. § 101 and 35 U.S.C. § 112, first paragraph.

Respectfully submitted,

May 18, 2005
Date

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